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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/746,921	12/22/2000	Kevin J. Thorne	2265-15	2764

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EXAMINER

LEITH, PATRICIA A

ART UNIT PAPER NUMBER

1655

DATE MAILED: 07/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/746,921	<b>Applicant(s)</b> THORNE ET AL.	
	<b>Examiner</b> Patricia Leith	<b>Art Unit</b> 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 5/9/06.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,8-10,32,33,35-37,44 and 48 is/are pending in the application.
- 4a) Of the above claim(s) 9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,8,10,32,33,35-37,44 and 48 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Claims 1, 8-10, 32-33, 35-37, 44 and 48 are pending in the application.

Claim 9 is withdrawn from consideration as being directed toward a non-elected invention.

Claims 1, 8, 10, 32-33, 35-37, 44 and 48 were examined on their merits.

Applicant's arguments toward the previous rejections are moot in-part due to the removal of those rejections. Applicant's arguments which are relevant to the following rejections are discussed *infra*.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 8, 10, 32-33, 36-37, 44 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Contstanz (US 5,047,031). It has been newly determined that the claims are obvious over this US Patent alone.

Constantz (US 5,047,031) discloses a bone cement composition which advantageously employs calcium phosphate compositions such as brushite (calcium

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hydrogen phosphate dihydrate) (column 1) , collagen such as Type I collagen and bone proteins such as bone morphogenic proteins(col. 6, lines 3-22).

Constantz did not specifically propose the amounts of ingredients as recited by the Instant claims.

It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal concentrations of components because concentration is an art-recognized result-effective variable which would have been routinely determined and optimized in the pharmaceutical art. Further, if there are any differences between Applicant's claimed method and that suggested by the teaching of the prior art, the differences would be appear minor in nature. Although the prior art do not teach all the various permutations of concentration ranges as claimed , it would be conventional and within the skill of the art to identify the optional concentrations of a given ingredient because Contstanz clearly taught that these parameters were to be suitably varied in order to formulate desired bone construction (see col. 6, line 26-col.7, line 3. Thus, the selection of appropriate concentration of ingredients to stabilize bone cement compositions for the intended purpose of replacing natural bone (e.g., teeth) is conventional and within the skill in the art.

Applicant argues that Constantz does not disclose the use of brushite alone.

However, the Examiner respectfully disagrees. Constantz recognizes that all of the disclosed calcium phosphate compositions may be beneficial in building artificial bone:

In selecting the calcium source, particularly where the calcium source not only serves as a source of calcium, but also in its neutralizing capacity, it may also serve as a source of phosphate. Therefore, in providing the various combinations, one must consider what calcium phosphate product is desired, since for the most part, the resulting product will be dependent upon the ratio of calcium and phosphate in the mixture. For brushite and monetite, a 1:1 ratio is desired. For octacalcium phosphate, a 1.33:1 ratio is desired. For tricalcium phosphate, a 1.5:1 ratio is desired. For hydroxyapatite, a 1.67:1 ratio is desired. The particular mineral will also be affected by the pH, but since the pH of the mixture will generally be in the range of about 5-8, it is found that the calcium/phosphate ratio is overriding (col. 4, line 56-col.5, line 2)

Here, it is clear that Constantz recognizes the beneficial use of brushite, as well as other calcium-phosphate compounds such as monetite for example.

Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A.

Applicant further argues that the claimed composition has an unpredictable "above-average explant mass, histology score, and mineral mass" (p. 5, Arguments). However, these are deemed to be intrinsic abilities of brushite, a calcium-phosphate bone-replacement source which was already used in the prior art. "Products of identical chemical composition can not have mutually exclusive properties. "A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the

identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). The Examiner cannot see any unexpected results with regard to the composition as a whole; for example, the composition of claim 1. It appears that Applicants have combined known, suitable ingredients for creating bone cement, lacking any evidence to the contrary.

Claims 1, 8, 10, 32-33, 35-37, 44 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Contstanz (US 5,047,031) in view of Damien et al. (5,563,124).

The teachings of Contstanz were discussed supra. Contstanz did not teach the specific use of Type I bovine tendon atelopeptide collagen.

Damien et al. (5,563,124) teaches an osteogenic product for bone repair which advantageously includes Type I bovine tendon atelocollagen (atelopeptide collagen): "Products of the present invention can optionally include components in addition to calcium carbonate and bone growth factor. For example, as noted above, a product can include a matrix forming material, such as collagen, fibrin or alginate. Preferred collagen is Type I bovine tendon atelocollagen"

One of ordinary skill in the art would have been motivated to use Type I bovine tendon atelocollagen (atelopeptide collagen) in the compositions taught by Constantz

because this type of collagen was known in the art to be suitable for use in bone matrices as disclosed by Damien et al. Therefore, one of ordinary skill in the art would have had a reasonable expectation that the addition of Type I bovine tendon atelocollagen would have provided acceptable structure when added to the bone compositions of Constantz especially because Constantz had already disclosed that Type I collagen was advantageous to use in the compositions.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on Monday - Friday 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Patricia Leith  
Primary Examiner  
Art Unit 1655

A handwritten signature in black ink, appearing to read 'Patricia Leith', written in a cursive style.

July 21, 2006